No. 25-45

IN THE
Supreme Court of the United States

CHATOM PRIMARY CARE, P.C., *et al.*, individually and on behalf of all others similarly situated,

Petitioners,

v.

MERCK & CO., INC.,

Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Third Circuit

BRIEF IN OPPOSITION

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QUESTION PRESENTED

Whether a decision made by the government in an adjudicative proceeding can create antitrust liability if the private party who requested the outcome from the government allegedly made a material misrepresentation.

CORPORATE DISCLOSURE STATEMENT

Pursuant to Supreme Court Rule 29.6, Respondent Merck & Co., Inc., discloses that it has no parent corporation and that no publicly held company owns 10% or more of its stock.

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BRIEF IN OPPOSITION

INTRODUCTION

Petitioners apparently regret the way that they litigated this case in the lower courts. They made no argument that a standalone misrepresentation exception to the *Noerr-Pennington* doctrine exists or applies to their case during summary judgment briefing in the district court, in their briefing on appeal, or at oral argument before the Third Circuit. Indeed, they affirmatively disclaimed invoking such an exception and instead argued that the well-established sham exception to *Noerr-Pennington* immunity applied. In seeking rehearing en banc, they changed course, and their

petition for certiorari reflects that same pivot. But neither rehearing nor certiorari is the time to ask for a do-over. The Third Circuit denied them one, and this Court should as well.

Merck manufactures a life-saving childhood vaccine for mumps. Since it was approved in 1967, there has been a 99% decrease in the incidence of that disease in this country. Two former Merck employees filed a False Claims Act (FCA) case against Merck in 2010, alleging that the vaccine had become less efficacious over time. The Government investigated and declined to intervene. After the FCA case was unsealed, Petitioners filed a follow-on antitrust case, based on the same factual allegations as the FCA case. The two cases were consolidated for discovery, and thereafter moved in lockstep.

The Third Circuit issued two, fully consistent decisions in these cases. In the FCA case, the court of appeals held that the relator-plaintiffs lacked evidence sufficient to create a triable fact as to whether Merck had made material misrepresentations to the Government about the vaccine. In the antitrust case, the Third Circuit similarly concluded that Petitioners had failed to show a triable fact as to whether Merck made misrepresentations to FDA—in a few submissions, decades ago—that rendered those submissions "sham" petitioning and outside of *Noerr-Pennington*'s protection from antitrust liability.

Petitioners now seek certiorari from the antitrust case, asking this Court to address an argument they never made to the district court and disclaimed making on appeal. Petitioners' waiver is one among several serious vehicle problems that should lead this Court to deny first-instance review.

The petition presents an alleged split over whether *material* misrepresentations made during *adjudicative* proceedings are outside of *Noerr-Pennington*. But even if Merck had made any misrepresentations to FDA—and it did not—those alleged misrepresentations were neither material nor made in an adjudicative proceeding. Petitioners' expert, a former Commissioner of FDA acting with court permission, urged the head of FDA and several other high level public health officials to take action based on his view that the evidence in this case showed a need for a change to Merck's label. That was 2019. FDA took no action in response. Moreover, the proceedings where the alleged misrepresentations were made were ordinary regulatory submissions by Merck to FDA around the time FDA had required an increase in the amount of vaccine in a vial when it was released to the market. Nothing about those submissions bears any of the hallmarks of adjudicative decisionmaking. This case is thus twice-over excluded from the asserted split.

Nor is the question presented otherwise in need of this Court's attention. Petitioners' split collapses with barely a poke. The unpublished decision below—which turns on Petitioners' waiver—makes plain that the Third Circuit has not definitively resolved the question presented. The majority of Petitioners' other cases either do not address fraudulent misrepresentations, have been overruled, or predate key decisions from this Court expounding on the limits of the *Noerr-Pennington* doctrine. In any event, policing alleged fraud through the antitrust laws is like trying to fit a square peg into a round hole. There are myriad tools better suited to ferreting out and remedying such conduct. And Petitioners' arguments on the merits rest on a mistaken view of this Court's precedents.

This Court should deny the petition.

STATEMENT

I. FACTUAL BACKGROUND

A. Merck Develops A Mumps Vaccine.

Mumps was once a ubiquitous childhood disease in the United States. *See United States ex rel. Krahling* v. *Merck & Co.*, No. 10-4374, 2023 WL 8367939, at *1 (E.D. Pa. July 27, 2023) (*Krahling I*).[1] Mumps can result in death and was once the leading cause of brain inflammation and sudden onset deafness in the United States. *Id.*

Merck's mumps vaccine changed that. In 1967, thanks to the pioneering work of Merck's researcher Dr. Maurice Hilleman, Merck introduced the world's first effective mumps vaccine. From that point until 2022, "Merck was the sole licensed manufacturer of mumps vaccines in the United States." Pet. App. 5a. During that time, the incidence of mumps cases dropped by more than 99%. Pet. App. 42a.

The FDA-approved label on Merck's mumps vaccine conveys a host of information about the vaccine, including the vaccine's seroconversion rate, potency, and shelf life.

A vaccine's seroconversion rate measures a vaccine's ability to provoke an immune response. *United States ex rel. Krahling* v. *Merck & Co.*, No. 23-2553, 2024 WL 3664648, at *1 n.4 (3d Cir. Aug. 6, 2024) (*Krahling II*).

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[1] *Krahling* is a closely related False Claims Act case concerning the same underlying allegations. *See* Pet. App. 39a; *infra* pp. 10-14. Cites to "KrahlingAppx" refer to the Joint Appendix filed in the Third Circuit, No. 23-2553, Doc. Nos. 31-56. Cites to "Appx" and "Doc." follow Petitioners' convention. *See* Pet. 11 n.1.

Merck's mumps vaccine label refers to a 96% seroconversion rate. *Id.* at *3. This rate is based on particular clinical studies showing that the vaccine induced "mumps neutralizing antibodies in 96%" of those studies' participants. Appx6686.

"Potency 'describes the concentration of virus in each dose of vaccine' expected to trigger antibodies." *Krahling II*, 2024 WL 3664648, at *1. "It is measured by the units of tissue culture infectious dose ('$TCID_{50}$'), which is, put simply, the amount of live virus placed in a vaccine." *Id.* Potency can be referred to as a whole number or that number's logarithmic equivalent. As of the late 1990s, the labeled potency was the equivalent of 4.3 $\log_{10}$ $TCID_{50}$. *Id.* Since 2007, the labeled potency is the equivalent of 4.1 $\log_{10}$ $TCID_{50}$. *Id.* at *4. As described in more detail below, FDA concluded that the lower potency triggers a similar seroconversion rate.

Merck's mumps vaccine has a two-year shelf life. Pet. App. 46a. Like all vaccines with live viral cells, the mumps vaccine's potency decreases between initial release and its expiration, known as end-expiry. *Krahling II*, 2024 WL 3664648, at *2.

B. Merck Complies With FDA's Request That It Increase The Vaccine's Release Potency.

From 1967 until the late 1990s, Merck had understood the label's 4.3 $\log_{10}$ $TCID_{50}$ potency figure to refer to the minimum potency level in the vaccine at its *release* to the market. *Krahling II*, 2024 WL 3664648, at *2. FDA approved every vaccine lot for release, knowing its release potency. KrahlingAppx290-291.

In the late 1990s, as part of an effort to improve labeling consistency across drugs, FDA determined that

potency statements should be interpreted as reflecting the potency at *end*-expiry. *Krahling II*, 2024 WL 3664648, at *2. In 1999, FDA instructed Merck to increase the minimum release potency for future lots to 5.0 $\log_{10}$ $TCID_{50}$—the release potency that FDA calculated would sufficiently ensure 4.3 $\log_{10}$ $TCID_{50}$ at end-expiry. *Id.* Merck complied. *Id.*

Several months later, a separate FDA division "issued Merck a Form 483 for failing to report that certain vaccine lots, manufactured prior to the increase in potency," fell below the label's potency statement by end-expiry. *Id.* A Form 483 "notifies the company's management of objectionable conditions." *Krahling I*, 2023 WL 8367939, at *3. Merck responded that those pre-potency-increase lots "were within the expected range based on historical trends." Appx7900.

FDA followed up with a Warning Letter directing Merck to submit an analysis of the expected end-expiry potency range for the lots released to the market before the potency increase. Pet. App. 47a-48a. Merck provided the requested analysis, explaining that "the expected average potency at expiry is 3.6 $\log_{10}$ $TCID_{50}$/dose." *Id.* An initial draft response had also stated that Merck "released to market 225 lots * * * that had an end-expiry potency potentially lower than 4.3 $\log_{10}$ minimum." Pet. App. 48a (citation omitted). But because FDA had requested an analysis of the expected end-expiry range and had approved each lot that was released, Merck's as-submitted response focused on the expected end-expiry potency.

In two instances, testing on pre-potency-increase lots showed that they *did* test below 4.3 $\log_{10}$ $TCID_{50}$ at end-expiry. Merck alerted FDA by filing a Biologics Product Deviation Report each time. *Id.* Among other

things, these reports noted that the higher release potency Merck was now using at FDA's request would ensure the labeled potency was satisfied through end-expiry. Appx9732, Appx9739. FDA did not request further action.

Since FDA's requested increase in release potency, Merck has tracked the potency level of the vaccine until after its end-expiry. Although some Merck employees had been concerned the increase would be insufficient to ensure the vaccine's potency would meet the label's stated potency at end-expiry, Pet. App. 49a-50a, those concerns proved unfounded. Merck's FDA-approved stability program has found no instances of any deviation from the labeled potency statement through end-expiry. KrahlingAppx16370-71.

C. Merck Runs A Study To Potentially Allow Merck To Lower The Potency Statement.

When FDA directed Merck to increase the release potency in 1999, neither FDA nor Merck thought the increase would necessarily be permanent. After all, the vaccine had proven over 99% effective at the lower release potency used from 1967 through 1999. Merck and FDA discussed a clinical trial, eventually known as Protocol 007, to support reducing the labeled potency level. Pet. App. 50a.

This trial involved two types of tests, or assays, which were jointly designed with FDA and run in different labs: "(1) a plaque reductions neutralization assay ('PRN') and (2) an enzyme-linked immunosorbent assay ('ELISA')." *Id.* According to FDA, data from this trial could support a label change if the seroconversion rate for the lower-potency vaccine was roughly the same as the rate for the then-current vaccine. Pet. App. 51a.

FDA approved the PRN's final design, and Merck conducted the assay in one of its research labs. After a technician working in that lab reported to FDA that Merck was improperly recounting certain data, FDA conducted a thorough investigation and ultimately issued Merck a Form 483 observing that "raw data [was] being changed with no justification." Pet. App. 52a.

Merck cooperated with FDA's investigation and filed a formal response to the Form 483. Merck explained, among other things, that its "reanalysis of the data set revealed 'no evidence of a difference between the corrected and uncorrected data sets with respect to seroconversion.'" *Krahling II*, 2024 WL 3664648, at *4.

In the end, because no protocol for a reanalysis had been set in advance, FDA declined to accept the corrected data sets. *Id.* at *4 & n.16. FDA permitted Merck to submit the original data sets from the PRN to support a potential label change. *Id.*

D. FDA Grants Merck's Applications To Lower The Potency Statement.

In January 2004, Merck submitted a supplemental Biologics License Application to FDA requesting to lower the label's potency statement from 4.3 to 4.1 $\log_{10}$ $TCID_{50}$. Pet. App. 53a. To support its application, and as instructed by FDA, Merck analyzed the correlation between the data from the Protocol 007 PRN and ELISA assays. Pet. App. 52a-53a.

Three years later, FDA informed Merck that it would not approve the application, based mainly on an insufficient quantity of data. *Id.* However, FDA said that scientific developments now permitted Merck to support its application with only ELISA data

and invited Merck to amend its Application accordingly. *Id.*

Merck did so, and FDA ultimately approved Merck's Application in December 2007. *Id.* By this point, however, Merck had been using a 5.0 $\log_{10}$ $TCID_{50}$ release potency for eight years in the United States (and in other countries). Merck opted against introducing the manufacturing complexities that would come from reducing the minimum release potency in the United States.

E. FDA Approves GSK's Mumps Vaccine.

In 1997, GSK began the process of seeking an FDA license to sell its mumps vaccine in the United States. Pet. App. 54a. Because Merck's vaccine was already on the market, GSK understood that its clinical trials had to demonstrate that its vaccine was "non-inferior" to Merck's vaccine. Pet. App. 53a. GSK chose to do that by attempting to "mirror[] Merck's label." Pet. App. 54a.

GSK's path to the U.S. market was hindered by setbacks that were entirely internal to GSK. GSK faced safety questions from FDA, budget constraints, profitability questions, and uncertainty over whether the market was moving from a trivalent vaccine product (measles, mumps and rubella) to a quadrivalent vaccine (those same three plus varicella). Pet. App. 54a-57a, 58-59a. GSK deprioritized its pursuit of U.S. licensure in 2000, only to reprioritize it in 2010. Pet. App. 55a-57a; Appx400. GSK later testified that five specific factors drove the timing of its vaccine development; none of those factors were GSK's inability to match the allegedly inflated seroconversion rate on Merck's label. Pet. App. 59a.

In 2011, GSK informed FDA that it wanted to use the same ELISA assay Merck had used in Protocol 007 in GSK's next phase of clinical studies. Pet. App. 57a. This assay had become commercially available in 2009, "when Merck's lab was purchased by an independent research company." *Id.* FDA granted GSK permission to use that assay in 2012. *Id.*

In 2021, GSK submitted a license application to FDA for its mumps vaccine. FDA approved that vaccine as non-inferior to Merck's in 2022. Pet. App. 60a.

During the time GSK was seeking FDA approval, Merck had an internal "Competitive Defense Task Force," which internal marketing documents describe as part of an "initiative[] to delay and disrupt the launch of" GSK's vaccine in the United States. Pet. App. 45a. Among other things, this task force considered whether to market Merck's vaccine directly to consumers and oversaw "head-to-head studies with" GSK's vaccine. Appx5289. The task force had no inside information as to GSK's decisionmaking, company priorities, or communications with FDA, and it played no role in drafting or submitting the Form 483 or Warning Letter responses or the Biologics Product Deviation Reports to FDA that are the subject of this petition.

II. PROCEDURAL HISTORY

1. The petition arises from the latter-filed of two consolidated cases.

The first case was filed in 2010 by two former Merck employees who brought an FCA suit against Merck alleging that Merck fraudulently conducted the PRN assay as part of Protocol 007 to hide from FDA that its mumps vaccine had become less efficacious over time. *United States ex rel. Krahling* v. *Merck & Co.*, 44 F.

Supp. 3d 581, 587-588 (E.D. Pa. 2014). The United States declined to intervene. *Krahling II*, 2024 WL 3664648, at *5.

In 2012, after the FCA case was unsealed, Petitioners filed this suit "based on the same allegations," asserting that Merck's "manipulation and misrepresentation of the seroconversion rate of the Mumps Vaccine" to FDA "led to Defendant's monopoly of the relevant market in violation of the Sherman Act." *Krahling*, 44 F. Supp. 3d at 588. According to Petitioners, Merck made misrepresentations to FDA in a few submissions around the time of the potency increase, which led to Merck unlawfully maintaining a monopoly over the mumps-vaccine market. Petitioners' multistep theory was that those alleged misrepresentations were the reason FDA did not make Merck change its label, a label change would have made it easier for GSK to show non-inferiority, and if it had been easier for GSK to show non-inferiority, GSK would have brought its vaccine product to market sooner, which would have allowed Petitioners to pay less. Pet. App. 20a, 60a.

GSK is not a party to this suit, or any other case involving these alleged facts. GSK maintains that the timing of its market entry was driven by factors that have nothing to do with Merck. *See supra* pp. 9-10.

The district court consolidated the FCA and antitrust cases. The United States, including the CDC and FDA, were both involved in and had knowledge of the evidence produced in the three-and-half years of discovery that followed. *Krahling II*, 2024 WL 3664648, at *7 n.35; *Krahling I*, 2023 WL 8367939, at *14-15.

After discovery, Petitioners, joined by the relators in the FCA action, requested permission from the court for their joint expert—former FDA Commissioner Dr. David Kessler—to make a submission directly to the heads of FDA, CDC, and the Department of Health and Human Services detailing what he said amounted to misstatements by Merck to FDA creating an urgent public health issue around Merck's mumps vaccine. *Krahling II*, 2024 WL 3664648, at *8; Appx301. The court allowed this submission specifically "so that those officials [could] determine what response, if any, is appropriate to address any potential public health issue." Appx301.

Dr. Kessler's submission occurred in 2019. It addressed the *same* label statements that Petitioners contend FDA would not have allowed to remain on Merck's mumps vaccine label if it had known Merck's misrepresentations. *Krahling II*, 2024 WL 3664648, at *8. According to Dr. Kessler, his findings implicated a "significant public health concern," and he urged the agencies to act by "[r]evising the labels for Merck's mumps-containing vaccines to accurately reflect what is known about how well this vaccine is actually working today." KrahlingAppx15619-21. Merck simultaneously submitted its own responses to Dr. Kessler's analysis. KrahlingAppx15623-718.

FDA has a statutory duty to "promptly" revise vaccine labels if it "becomes aware of new information" showing a label is materially misleading. 21 U.S.C. § 355(o)(4)(A). Six years have passed. FDA has taken no action to change the label of Merck's mumps vaccine, or any other action, in response to Dr. Kessler's submission.

2. Merck moved for summary judgment in both cases. The district court ruled on the motions on the same day.

In the FCA case, as relevant here, the court agreed with Merck that no reasonable jury could find that any alleged falsity was material to CDC's decision to purchase Merck's vaccines. *Krahling I*, 2023 WL 8367939, at *9, *16.

In the antitrust case, as relevant here, Merck argued that *Noerr-Pennington* prevented Petitioners from basing their antitrust claim on statements in Merck's submissions to FDA and that Petitioners could not establish causal antitrust injury. Pet. App. 64a. Petitioners argued that *Noerr-Pennington*'s exception for "sham" petitioning applied because Merck had made misrepresentations in three of the many hundreds of submissions by Merck to FDA related to its mumps vaccine: Merck's "2001 responses to the FDA Form 483 and Warning Letter and [Biologics Product Deviation Reports]." Opposition to Motion for Summary Judgment 58, D. Ct. Dkt. No. 295 (Feb. 20, 2020) ("MSJ Opp."). The district court denied Merck's motion, holding a genuine dispute of fact existed as to application of the sham exception to these documents and as to whether Petitioners could show causal antitrust injury. Pet. App. 69a-70a, 72a-75a. But recognizing that other jurists might disagree with those conclusions, the district court certified an interlocutory appeal. Appx95-98.

3. On appeal, the Third Circuit heard argument on the two cases on the same day. It affirmed the judgment in Merck's favor in the FCA case and reversed

the denial of summary judgment to Merck in the antitrust case. In so doing, the Third Circuit made the decisions in the two cases consistent.

In the FCA case, the court agreed that there was no triable fact as to materiality. *Krahling II*, 2024 WL 3664648, at *9. It highlighted the Government's actual "knowledge of the facts concerning the alleged misrepresentations and fraudulent acts as to testing, potency, shelf-life and the like." *Id.* at *8. The Government, despite having participated at the district court level in the summary judgment hearing, did not participate in the appeal.

In the antitrust case, the court issued an unpublished, non-precedential opinion holding that there was no triable fact as to *Noerr-Pennington*'s sham exception. Pet. App. 3a-5a. The court did not reach the causal antitrust injury issue. Pet. App. 26a n.18. It also did not address "whether Merck's communications with the FDA should be characterized as adjudicative or legislative." Pet. App. 15a n.10.

In analyzing the relevant submissions, the court concluded that Petitioners "failed as a matter of law to satisfy" the sham exception's "subjective prong." Pet. App. 16a. Citing this Court's decision in *Professional Real Estate Investors, Inc.* v. *Columbia Pictures Industries, Inc.*, 508 U.S. 49 (1993) (*PRE*), the Third Circuit explained that the subjective prong asks whether the defendant "subjectively intended to 'use * * * governmental process—as opposed to the outcome of that process—as an anticompetitive weapon.'" Pet. App. 11a-12a (ultimately quoting 508 U.S. at 61).

Petitioners had conceded "that they 'do not allege injury from the process at all, never mind an abuse of that process.'" Pet. App. 15a. That concession doomed

their invocation of the sham exception: "By definition, Merck cannot have intended to commit a sham if it sought to use the result of petitioning the government (*i.e.*, FDA-approved drug label claims)—as opposed to the petitioning itself—to harm competition." Pet. App. 16a. This was so even "assum[ing] that Merck's petitions would lack objective merit without th[e] alleged falsehoods." Pet. App. 15a.

In a footnote, the court observed that "[s]everal of our sister circuits appear to recognize a standalone exception to *Noerr-Pennington* immunity for petitions—made in an adjudicative setting—containing fraudulent misrepresentations." Pet. App. 16a n.12. But the court declined to consider whether that exception applied because Petitioners had "waived any argument based on that purported exception" by "expressly disclaim[ing] reliance on" it in their brief. Pet. App. 17a n.12. The court continued that it would not address this argument even if Petitioners' waiver were merely a forfeiture. That is because, based on the court's "read[ing]" of Third Circuit precedent, the circuit has "reject[ed] a standalone [misrepresentation] exception." Pet. App. 18a n.12. The court noted that the dissent read Third Circuit precedent differently. *Id.*

According to the dissent, "[a]lthough our Court has not expressly recognized a misrepresentation exception, our precedent does not foreclose it." Pet. App. 30a. The dissenting judge would have recognized such an exception. Pet. App. 32a-34a.

In seeking rehearing en banc, Petitioners argued for the first time in favor of adoption of a standalone misrepresentation exception. Their rehearing petition was denied. Pet. App. 90a-91a.

REASONS FOR DENYING THE PETITION

I. THIS CASE IS AN EXCEPTIONALLY POOR VEHICLE TO RESOLVE THE QUESTION PRESENTED.

A. This Case Does Not Implicate The Alleged Split.

Petitioners say the circuits are split on whether the *Noerr-Pennington* doctrine should have a standalone exception for material misrepresentations made to the government during adjudicative proceedings. Pet. 16-23. But the alleged misrepresentations here were not material to FDA's decisionmaking about the seroconversion rate listed on Merck's label—which remains on the label today—nor were they made during an adjudicative proceeding; they were part of FDA's ordinary regulatory oversight of vaccines. This case thus does not implicate the petition's asserted split.

1. The alleged misrepresentations did not materially affect any statement on Merck's label.

Petitioners' theory is that Merck made the alleged misrepresentations in the Form 483 and Warning Letter responses and the Biologics Product Deviation Reports so that FDA would not take action requiring Merck to change the statement on its label articulating the seroconversion rate from specific clinical studies that Petitioners asserted (based on no testing) is no longer the actual seroconversion rate for the vaccine. *See* Pet. App. 6a-7a, 20a-21a. If those alleged misrepresentations had materially affected FDA's view of the contents of Merck's label, those statements would have been changed once FDA knew the sup-

posed truth. That is because a material misrepresentation "actually alter[s] the outcome of the proceeding." *Mercatus Grp., LLC* v. *Lake Forest Hosp.,* 641 F.3d 834, 843 (7th Cir. 2011). The unique history of this case, however, makes clear that the alleged misrepresentations here did not materially affect the label's contents.

Not only did the Government participate in this case because of the parallel FCA suit, including extensive involvement in discovery, but this case involves an unusual additional tell of FDA's knowledge. Six years ago, Petitioners received court permission for their expert to go directly to the FDA Commissioner detailing his concerns about what the discovery record showed about Merck's label and the alleged misrepresentations Merck made in connection with that label. *See supra* pp. 12-13. Their expert's submission discussed the same supposed misrepresentations invoked by Petitioners. *See* Doc. 33 at 53-54 ("CA3 Opening Br."). All of this ensured the Government had actual knowledge "concerning the alleged misrepresentations and fraudulent acts as to testing, potency, shelf-life and the like." *Krahling II*, 2024 WL 3664648, at *8.

Yet, at no point since these suits were filed in 2010 and 2012 has FDA taken a single step towards changing Merck's label in response. Pet. App. 21a. That inaction is significant. Under 21 U.S.C. § 355(o)(4)(A), "Congress has imposed on the FDA a duty to initiate a label change '[i]f the Secretary becomes aware of new information * * * that the Secretary determines should be included in the labeling of the drug.'" *Merck Sharp & Dohme Corp.* v. *Albrecht*, 587 U.S. 299, 324 (2019) (Alito, J., concurring). And "if the FDA declines

to require a label change despite having received and considered information regarding a new risk, the logical conclusion is that the FDA determined that a label change was unjustified." *Id.* (citing *United States* v. *Chemical Found., Inc.*, 272 U.S. 1, 14-15 (1926) (discussing the presumption of regularity).

FDA's continued inaction in the face of its statutory duty to act can only mean that the agency does not consider the label to be misleading, *regardless of the statements that Petitioners view as misrepresentations*. These alleged misrepresentations were not in any way outcome determinative as to any statement on Merck's label.

2. The alleged misrepresentations did not occur within "adjudicative proceedings."

Courts consider several factors when determining whether a particular proceeding was legislative or adjudicative. *See, e.g.*, *Mercatus*, 641 F.3d at 845-847. These include whether the agency "compile[d] an evidentiary record through formal proceedings," *id.* at 845; "whether the governmental actions at issue were matters of discretionary authority or were instead guided by more definite standards susceptible to judicial review," *id.* at 846; and whether the agency "issue[d] written findings," *Kottle* v. *Northwest Kidney Ctrs.*, 146 F.3d 1056, 1062 (9th Cir. 1998).

Here, these factors point in one direction: Merck's Form 483 and Warning Letter responses, and its Biologics Product Deviation Reports, were not part of any adjudication. They were three of hundreds of private submissions Merck made to FDA in connection with FDA's oversight of Merck's vaccine. They were not part of "formal proceedings" that FDA publicly conducted, or part of "compil[ing] an evidentiary record"

for such proceedings. *Mercatus*, 641 F.3d at 845. FDA did not issue any written decision resolving any factual disputes, much less decisions applying standards susceptible to judicial review. FDA instead simply received Merck's submissions as part of its ordinary regulatory oversight and opted to require no further action by Merck. This is not the stuff of adjudication.[2]

B. Petitioners Have Waived The Question Presented.

This case is marred by another serious vehicle issue: Petitioners waived their argument that *Noerr-Pennington* does not apply to Merck's submissions under a misrepresentation exception "separate and apart from the sham exception." Pet. 31.

1. In the Third Circuit, Merck suggested that Petitioners "may seize on the fact that two courts of appeals have held that in the context of an adjudicatory proceeding, fraudulent misrepresentations can take petitioning outside of *Noerr-Pennington*'s immunity." CA3 Opening Br. 32. Petitioners' response brief did the opposite: It dismissed those cases as "address[ing] a separate exception for fraudulent misrepresentation—an exception the Third Circuit rejects." Doc. 44

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[2] In the lower courts, the parties litigated the sham exception only as to the potency-related "Form 483, Warning Letter, and BPDR." Pet. App. 34a & n.8 (Schwartz, J., dissenting); *see also* CA3 Response Br. 58 (not disputing that these are the relevant submissions); MSJ Opp. 58 (identifying these submissions as the alleged shams). Petitioners have thus waived any argument that the supplemental Biologics License Application was a sham. And although the Third Circuit could have excused the waiver and expanded the scope of potential shams to include this Application, *see* Pet. App. 14a-15a, the murkiness surrounding what submissions to FDA are at issue here is itself a serious vehicle problem.

at 65 ("CA3 Response Br."). Petitioners chose to exclusively argue the sham exception in their brief and at oral argument.

As the Third Circuit recognized, Petitioners' express statement that they were not arguing for a standalone misrepresentation exception constitutes waiver. Pet. App. 16a n.12. That waiver carries through to this Court. *Sprietsma* v. *Mercury Marine, a Div. of Brunswick Corp.*, 537 U.S. 51, 56 & n.4 (2002) ("Because this argument was not raised below, it is waived."). This Court's practice against considering waived questions "promot[es] the creation of an adequate factual and legal record," *Adams* v. *Robertson*, 520 U.S. 83, 90-91 (1997); gives parties "the opportunity to test and refine their positions before reaching this Court," *id.* at 91; and affords this Court "the benefit of a * * * reasoned opinion on the merits," *Bankers Life & Cas. Co.* v. *Crenshaw*, 486 U.S. 71, 80 (1988).

To be sure, the panel *sua sponte* opined on the existence of a standalone misrepresentation exception. But the panel did so in the context of explaining why—even if Petitioners' waiver were instead a forfeiture—the panel would not excuse that forfeiture. Pet. App. 17a-18a. As it reaches this Court, then, Petitioners really seek to have this Court review the correctness of the panel's determination that if Petitioners' litigation conduct only amounted to forfeiture, that forfeiture should be excused. That is not a question fit for this Court's review.

2. Petitioners' attempts to get around their waiver distort what happened below.

First, Petitioners insist (at 27-28) that they "seek[] to litigate the same question that they teed up below"

and that the panel "passed upon" that question. That is inaccurate.

Petitioners argued below that "'successful' material misrepresentations *fall under the sham exception*." CA3 Response Br. 63 (emphasis added). That framing had consequences. Whereas Petitioners' proposed misrepresentation exception necessarily focuses on the *outcome* of a proceeding, the sham exception concerns a defendant's abuse of "*process*—as opposed to the *outcome* of that process." *City of Columbia* v. *Omni Outdoor Advert., Inc.*, 499 U.S. 365, 380 (1991). But Petitioners had "concede[d] that they 'do not allege injury from the process at all, never mind an abuse of that process.'" Pet. App. 15a. That concession decided this case. Pet. App. 15a-17a.

Petitioners' litigation strategy deprived the courts below of answering the question presented in the petition. By embracing the sham exception—and then arguing themselves out of its ambit—Petitioners never asked for a ruling that *Noerr-Pennington* immunity is inapplicable under some other theory. The fact that the panel nonetheless opined on a misrepresentation exception in a drive-by footnote is no reason to grant Petitioners a do-over.

Second, Petitioners now say (at 27) that when they rejected reliance on a misrepresentation exception, they were merely "acknowledg[ing] * * * binding Third Circuit precedent." That is revisionist history. Despite being represented by sophisticated counsel, Petitioners did not append to their so-called acknowledgment any boilerplate statement preserving the argument for future review.

C. The Question Presented Is Not Outcome Determinative.

Finally, this Court should deny certiorari because the question presented "is irrelevant to the ultimate outcome of the case." Stephen M. Shapiro *et al.*, Supreme Court Practice § 4.4(F) (11th ed. 2019). Even if Petitioners prevailed on the *Noerr-Pennington* issue, they would lose on antitrust causation. Petitioners cannot point to a genuine dispute of fact over whether Merck caused GKS's delay and thus their injury. *See Brunswick Co.* v. *Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 489 (1977); Pet. App. 26a n.18 (panel reserving this question).

No reasonable jury could find that GSK would have secured FDA licensure and entered the market sooner than it did "but for" Merck's alleged "exclusionary conduct." *Meijer, Inc.* v. *Biovail Corp.*, 533 F.3d 857, 862 (D.C. Cir. 2008). GSK's corporate designee identified five specific factors that exclusively drove the timing of the GSK vaccine's timing and development. Pet. App. 59a. None of those were GSK's inability to match the allegedly inflated statement on Merck's label. GSK instead faced internal debate about whether to focus only on adult vaccines, whether the market had moved past a trivalent product to a quadrivalent product, and so on. GSK's corporate designee specifically testified that the company "was not aware of any statement on Merck's product labels * * * that foreclosed GSK from commercializing [its] vaccine in the United States." *Id.* That testimony tracks the documentary evidence. *See* Pet. App. 53a-58a.

And even if any label statements *did* influence the GSK vaccine's development, Petitioners lack any

evidence that FDA would have approved GSK's vaccine sooner than it did. The fact that FDA has not required Merck to change its label, despite now knowing of the alleged misrepresentations and having a statutory duty to act in the face of material new information, conclusively shows that FDA *would not* have required Merck to take any action and thereby alter the non-inferiority showing needed to approve GSK's market entry. *See supra* pp. 17-18.

II. PETITIONERS EXAGGERATE THE SPLIT.

Petitioners get it exactly backwards when they say that "all but two [circuits] have weighed in on the question presented." Pet. 18. In reality, *only two*—at most—have. To the extent there is a split on the question presented, it is academic and not in urgent need of resolution.

A. The Third Circuit Has Not Definitively Taken A Position On The Question Presented.

The petition is built on the false premise that "the Third Circuit has flat-out 'reject[ed] a standalone exception to *Noerr-Pennington* immunity for petitions containing fraudulent misrepresentations.'" Pet. 17. In fact, as the dissent explained, Third Circuit precedent "counsels against tolerating a party's material misrepresentations in petitioning activity during an adjudicative proceeding." Pet. App. 30a.

The Third Circuit currently does that through the sham exception: "[W]here the petitioning effort allegedly involves misrepresentations, the Court, at the first step, must 'determine whether the petition was objectively baseless * * * without regard to those facts

that the plaintiff alleges the petitioner misrepresented.'" *Armstrong Surgical Ctr., Inc.* v. *Armstrong Cnty. Mem'l Hosp.*, 185 F.3d 154, 158 n.2 (3d Cir. 1999) (quoting *Cheminor Drugs, Ltd.* v. *Ethyl Corp.*, 168 F.3d 119, 123 (3d Cir. 1999)) (brackets and emphasis omitted). Thus, as the Third Circuit stated in *Cheminor*, "a *material* misrepresentation that affects the very core of a litigant's * * * case will preclude *Noerr-Pennington* immunity." 168 F.3d at 124.[3]

Even so, as the dissent below stated, Third Circuit "precedent does not foreclose" a standalone fraud exception. Pet. App. 30a. The majority recognized that "reasonable minds can and do differ" on its interpretation of Third Circuit precedent. Pet. App. 18a. And because the decision below is unpublished, the majority's view that circuit precedent forecloses a fraud exception separate and apart from the sham exception does not bind future panels.

The question presented thus remains unanswered in the Third Circuit. And with the roadmap offered by the dissent, the court may likely have an opportunity to answer that question for itself. This Court should not short-circuit that process.

B. Eight Circuits Cited By Petitioners Have Not Answered The Question Presented.

Petitioners' contention (at 21-22) that the First, Second, Fifth, Sixth, Eighth, Eleventh, D.C., and Federal

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[3] The Federal Trade Commission has recognized that "the Third Circuit has analyzed misrepresentation[s] as raising the 'sham' exception." *In the Matter of Union Oil Co. of Cal.*, 138 F.T.C. 1, 41 (2004) (cited at Pet. 18). The FTC observed that both *Cheminor* and *Armstrong* "leave room for finding misrepresentation a sham under appropriate circumstances." *Id.* at 43.

Circuits have all addressed the question presented is also wrong. Petitioners' cases either do not address intentional misrepresentations, have since been overruled, or are otherwise hopelessly stale. None of these cases reflect a settled view on the question presented.

1. The decisions least relevant are those from the Second, Eighth, and Federal Circuits.

Petitioners' Second and Eighth Circuit cases do not implicate the split because they do not concern misrepresentations. *See Juster Assocs.* v. *City of Rutland*, 901 F.2d 266, 269 (2d Cir. 1990); *Razorback Ready Mix Concrete Co.* v. *Weaver*, 761 F.2d 484, 485-486 (8th Cir. 1985).

The closest the Second Circuit's *Juster* decision comes to the question presented is an aside suggesting *Noerr-Pennington* is inapplicable where governmental "processes are invoked by means that violate ethical standards applicable to adjudicative tribunals." 901 F.2d at 271. But the case *Juster* cites in support of that proposition concerns conduct that clearly sounds in the established sham exception: "numerous meritless appeals" and "the solicitation and subsidization of meritless litigation." *Landmarks Holding Corp.* v. *Bermant*, 664 F.2d 891, 896 (2d Cir. 1981).

As for the Eighth Circuit, Petitioners apparently rely on that court's citation to Fifth and D.C. Circuit decisions. *See* Pet. 21. But *Razorback* cited those cases in support of its view that the sham exception focuses on "access-barring conduct." 761 F.2d at 487. This Court has since rejected that view. *See Omni*, 499 U.S. at 381 (access-barring conduct "does not necessarily render [a petition] a 'sham'").

The Federal Circuit has not addressed the question presented either. Petitioners' case—*TransWeb, LLC*

v. *3M Innovative Properties Co.* (at 22)—concerned "a *Walker Process* antitrust violation," which arises when a party seeks to enforce "a fraudulently-obtained patent." 812 F.3d 1295, 1306 (Fed. Cir. 2016). Nothing in *TransWeb* suggests that the Federal Circuit applies *Walker Process* to anything other than that "very specific conduct." *TransWeb*, 812 F.3d at 1311 (quoting *Nobelpharma AB* v. *Implant Innovations, Inc.*, 141 F.3d 1059, 1071 (Fed. Cir. 1998)).

Although *TransWeb* references the sham exception, it did so in explaining that the Federal Circuit also applies the sham exception in the patent context—not that it applies *Walker Process* beyond that context. *See* 812 F.3d at 1311-12. Petitioners misunderstand that case in arguing to the contrary.

2. As for Petitioners' citation (at 22) to the Fifth Circuit's decision in *Woods Exploration & Producing Co.* v. *Aluminum Co. of America*, 438 F.2d 1286 (5th Cir. 1971), the holding in that case was overruled by *California Motor Transport Co.* v. *Trucking Unlimited*, 404 U.S. 508 (1972). In *Woods*, the Fifth Circuit declined to apply *Noerr-Pennington* because it believed the doctrine did not extend to the "adjudicative" context and instead applied only to "action designed to influence policy." 438 F.3d at 1296-98. This Court extended *Noerr-Pennington* to the adjudicative context the following year. *See California Motor*, 404 U.S. at 510-511; *Reaemco, Inc.* v. *Allegheny Airlines*, 496 F. Supp. 546, 557 n.6 (S.D.N.Y. 1980) (recognizing that *California Motor* implicitly overruled *Woods*).

Woods also concerned the unique situation where there was "no opportunity" for the government agency to "meaningful[ly] supervis[e]" the defendants or "verif[y]" the facts presented by the defendants, which

were in the defendants' "exclusive control." 438 F.2d at 1295. The opposite is true here, where FDA itself determined what potency increase Merck should use in 1999 and approves the release of every lot of vaccine to the market knowing the release potency.

3. Petitioners say (at 21) that the Sixth and D.C. Circuits (as well as the Eighth Circuit) treat fraudulent petitions as "shams." But the decisions cited by Petitioners—*Potters Medical Center* v. *City Hospital Association*, 800 F.2d 568 (6th Cir. 1986), *Israel* v. *Baxter Laboratories, Inc.*, 466 F.2d 272 (D.C. Cir. 1972), and *Razorback* (8th Cir.)—predate this Court's decision in *PRE*.

Decisions predating *PRE* cannot reasonably be read to implicate Petitioners' alleged split because *PRE* formalized and articulated the modern sham exception. Prior to that case, there was "confusion over the meaning of 'sham.'" *PRE*, 508 U.S. at 61; *see also Allied Tube & Conduit Corp.* v. *Indian Head, Inc.*, 486 U.S. 492, 507 n.10 (1988) (criticizing the use of "sham" to cover any activity a court "deem[s] unworthy of antitrust immunity"). To the extent *Potters*, *Israel*, and *Razorback* surmised that a fraudulent misrepresentation could constitute a "sham," they did so according to a since-discarded understanding of that term. They thus do not reflect these circuits' views on the law as currently articulated by this Court.

Petitioners all but admit as much. They do not cite any case from the Sixth or Eighth Circuits post-dating *PRE* suggesting that those circuits would abide by *Potters* or *Razorback*.

Petitioners attempt to bolster their argument with respect to D.C. Circuit precedent by citing *Whelan* v. *Abell*, 48 F.3d 1247 (D.C. 1995), but that case does not

help them. As Petitioners admit (at 21), *Whelan* does not clearly articulate the D.C. Circuit's position on the question presented. *Whelan* also concerned petitioning that clearly sounds in the established sham exception: "a bad faith use of legal process" that was instituted for publicity's sake and that concerned "frivolous charges." 48 F.3d at 1250. It was this abuse of the legal process—not, as Petitioners argue (at 17), the eventual show-cause order issued by a state agency—that the plaintiffs argued "directly caused" them harm. 48 F.3d at 1250.

4. Petitioners' Eleventh Circuit decision—*St. Joseph's Hospital, Inc.* v. *Hospital Corp. of America*, 795 F.2d 948 (1986) (cited at 22)—is likewise too old to implicate the alleged split.

The Eleventh Circuit relied entirely on *California Motor*'s observation that "[m]isrepresentations * * * are not immunized when used in the adjudicatory process." *Id.* at 955 (quoting 404 U.S. at 513). But *Omni* later clarified that *California Motor* was "limited" to "a context in which the regulatory process is being invoked genuinely, and not in a 'sham' fashion." 499 U.S. at 381-382. *PRE* then indicated that *California Motor* had not "decided * * * whether and, if so, to what extent *Noerr* permits the imposition of antitrust liability for a litigant's fraud or other misrepresentations." 508 U.S. at 61 n.6. Petitioners do not cite a case from the Eleventh Circuit post-dating this Court's clarifications.

5. Finally, Petitioners misinterpret *Amphastar Pharmaceuticals, Inc.* v. *Momenta Pharmaceuticals, Inc.*, 850 F.3d 52 (1st Cir. 2017). That case did not find "no immunity" where a drug company "intentionally conceal[ed]" a major fact before "a federal agency."

Pet. 17. The defendants convinced a private standard-setting organization to adopt a testing method covered by the defendants' patent without disclosing the patent; the FDA later required all drugmakers to use that method; and the defendants then filed a patent-infringement suit against the plaintiffs. *See* 850 F.3d at 54-55.

The only petitioning conduct at issue in *Amphastar* was the infringement suit—which did not involve misrepresentations. *See id.* at 56. The defendants "expressly declined" to seek *Noerr-Pennington* immunity for "their conduct before the" standard-setting organization or based "on the FDA's alleged adoption of" the testing method. *Id.* Indeed, *Amphastar* did not even squarely address whether the federal litigation was subject to *Noerr-Pennington*; the issue in that case concerned the scope of damages. *Id.* at 57-58.

C. The Alleged Division Of Authority Is Shallow And Cannot Be Resolved Here.

That leaves the Seventh and Ninth Circuits. But, even if the decision below represented the Third Circuit's conclusive position on the question presented (and it does not), this case would be a particularly poor vehicle for resolving any tension between the Third, Seventh, and Ninth Circuits because this case would come out the same way in all of these courts. There is thus no meaningful split between these courts.

The Seventh Circuit did not apply its misrepresentation exception in either of the cases cited by Petitioners (at 20) because the underlying petitioning did not occur in the adjudicative context. *See Mercatus*, 641 F.3d at 849; *United States Futures Exch., LLC* v. *Board of Trade of the City of Chi., Inc.*, 953 F.3d 955, 960 (7th Cir. 2020). The same is true here. *See supra*

pp. 18-19. On top of that, in *Mercatus*, the Seventh Circuit cited Third Circuit precedent when stating that "there is little doubt that fraudulent misrepresentations may render purported petitioning activity a sham not protected from antitrust liability." 641 F.3d at 842 (citing *Cheminor*, 168 F.3d at 124).

As for the Ninth Circuit, Petitioners cite (at 20) *Kaiser Foundation Health Plan, Inc.* v. *Abbott Laboratories, Inc.*, 552 F.3d 1033 (9th Cir. 2009), but that case is far afield from this one. The Ninth Circuit there considered whether seventeen back-to-back patent-infringement lawsuits triggered the sham exception. *See id.* 1045-47. The court also discussed *Walker Process* fraud, *see id.* at 1047-51, but the Third Circuit likewise applies *Walker Process*. *See, e.g.*, *In re Lipitor Antitrust Litig.*, 868 F.3d 231, 266 (3d Cir. 2017).

To the extent Petitioners are relying on *Kaiser* for its general summation of Ninth Circuit law, that bottoms out on *Kottle*. *See Kaiser*, 552 F.3d at 1045 (quoting *Sosa* v. *DIRECTV, Inc.*, 437 F.3d 923, 938 (9th Cir. 2006) (in turn quoting *Kottle*, 146 F.3d at 1060)). But *Kottle* declined to apply its newly articulated exception because the plaintiff had failed to plausibly allege any misrepresentations. *See* 146 F.3d at 1063=64. Here, too, Merck made no misrepresentations that could trigger this exception. *See supra* pp. 16-18.

III. THE QUESTION PRESENTED IS OF LIMITED PRACTICAL EFFECT.

The question here is a narrow one. The sky has remained in place during the half-century-plus this Court has not exempted fraudulent misrepresentations from *Noerr-Pennington*. Petitioners give no reason why it will fall now.

1. Petitioners contend (at 24) that antitrust liability for misrepresentations is necessary to avoid "undermining the integrity of" the government. But there are myriad "other remedies"—better ones—to address intentional misrepresentations to the government. *See Omni*, 499 U.S. at 382 (observing that there "may be other remedies" to address conduct immunized under *Noerr-Pennington*). "The antitrust laws are not designed for all social ills. Antitrust protects the operation of private markets, not the operation of government." Frank H. Easterbrook, *Petitioning for Protection from Competition: A Comment*, The Political Economy of Regulation: Private Interests In The Regulatory Process, 93, 94 (FTC Law & Econ. Conf., Mar. 1984).

For starters, if FDA is concerned it was defrauded, the agency "is empowered to investigate suspected fraud." *Buckman Co.* v. *Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 (2001). Indeed, FDA prioritizes investigating "false statements to the FDA during the regulatory process." *Investigative Priorities*, FDA Office of Criminal Investigations.[4] Private citizens may also "report wrongdoing and petition the agency to take action." *Buckman*, 531 U.S. at 349. Such action includes seeking injunctive relief and civil penalties, as well as bringing a criminal prosecution. *See id.* (citing 21 U.S.C. §§ 332, 333(f)(1)(A), and 333(a)). FDA can also—indeed it must—require label revisions if it learns of misrepresentations affecting safety or efficacy. 21 U.S.C. § 355(o)(4)(A).

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[4] *Available at* https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/criminal-investigations/investigative-priorities/ (current as of Aug. 12, 2025).

More broadly, the Department of Justice has at hand numerous criminal statutes to punish intentional misrepresentations. *See, e.g.*, 18 U.S.C. § 1001 (false statements); *id.* § 1505 (obstruction); *id.* § 1512(c) (falsified documents). The Department can also seek redress under the FCA. 31 U.S.C. § 3730(a). Private parties can likewise sue under the FCA, *id.* § 3730(b), as the relators did here in the parallel action.

In cases involving a misrepresentation during an actual adjudication, the Department can bring a perjury charge. 18 U.S.C. § 1621. The court can order sanctions. And if an attorney made the misrepresentation, she can lose her license. *See* Model Rules of Pro. Conduct r. 3.3 (Candor Toward The Tribunal), r. 8.4 (Misconduct) (A.B.A. 2025).

These targeted remedies are better suited to protecting governmental integrity than the vagaries of antitrust law. The focus in an antitrust suit is not the misrepresentations themselves, but their "anticompetitive effect," which requires sloshing through a complicated burden-shifting framework. *United States* v. *Microsoft Corp.*, 253 F.3d 34, 58-59 (D.C. Cir. 2001) (per curiam). Tellingly, Petitioners do not cite a single case where the Government responded to a misrepresentation with an antitrust suit.

2. Petitioners' other arguments likewise do not hold up.

Petitioners argue (at 24) that this case is generically important because it concerns "the First Amendment"—albeit tangentially—"and the reach of federal antitrust law." This Court denies petitions involving those areas of the law every Term.

Petitioners also spotlight (at 25) that this case arises out of the Third Circuit. That cuts against certiorari, considering that the question presented is still unresolved there. *See supra* pp. 23-25.

And Petitioners' assertion that the drug-approval process is "particularly susceptible to manipulation" is based on a law-review article identifying "the opportunities that may exist for manipulating administrative *procedures*." Lars Noah, *Sham Petitioning as a Threat to the Integrity of the Regulatory Process*, 74 N.C. L. Rev. 1, 5 (1995) (emphasis added). The manipulation of procedure is exactly what the sham exception already addresses.

IV. THE DECISION BELOW IS CORRECT.

The Third Circuit correctly applied this Court's precedents to resolve this case the way Petitioners presented it: under the sham exception.

To the extent the court below even touched on the question presented, it was rightly skeptical of a standalone exception extending the Sherman Act to fraud on the government. Doing so would require courts to look behind government action to determine what effect, if any, the alleged misrepresentation had on that action. This is especially problematic in a case like this one, which concerns scientifically technical questions about statements made on a vaccine label. And, as the United States explained in opposing certiorari on this issue previously, because *Noerr-Pennington* also extends to petitioning before state agencies, Petitioners' proposed exception would require courts to "'look[] behind the actions of state sovereigns," which risks "federal intrusion into the state decision-making process." U.S. Br., *Armstrong Surgical Ctr.* v. *Armstrong Cnty. Mem. Hosp.*, (No. 99-905),

2000 WL 34005427, at *17 (June 2, 2000) (quoting *Omni*, 499 U.S. at 379) ("U.S. *Armstrong* Br.").

Petitioners fail to address these concerns.[5] They merely insist (at 29) that *Noerr-Pennington*'s scope is defined by the First Amendment's scope. But *Noerr-Pennington* immunity is not just a First Amendment doctrine. It is "a substantive principle of antitrust law—derived from the statutory text and purpose of the Sherman Act—that shields defendants from liability based on the notion that 'the federal antitrust laws do not regulate the conduct of private individuals in seeking anticompetitive action from the government.'" Pet. App. 19a (quoting *Omni*, 499 U.S. at 379-380) (brackets and ellipses omitted).

As this Court made clear in *Omni*, *Noerr-Pennington* extends to *all* efforts that genuinely seek government action, regardless of whether such efforts are "improper or even unlawful," because "antitrust laws regulate business, not politics." 499 U.S. at 381, 383. Indeed, "[i]n *Noerr* itself, where the private party 'deliberately deceived the public and public officials' in its successful lobbying campaign, [this Court] said that 'deception, reprehensible as it is, can be of no consequence so far as the Sherman Act is concerned.'" *Id.* at 383-384 (quoting *Eastern R.R. Presidents Conf.* v. *Noerr Motor Freight, Inc.*, 365 U.S. 127, 142 (1961)). That conclusion followed the Court's "recognition that

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[5] The American Antitrust Institute states that Petitioners' proposed exception "would not interfere with the separation of powers or federalism," without explaining how a court scrutinizing the integrity of the Executive Branch's or state agency's decisionmaking does not raise these exact concerns. Amicus Br. of Am. Antitrust Inst. 8.

the antitrust laws, 'tailored as they are for the business world, are not at all appropriate for application in the political arena.'" *Id*. at 380 (quoting *Noerr*, 365 U.S. at 141).

Petitioners rely heavily on *California Motor*'s statement that "misrepresentations, condoned in the political arena, are not immunized when used in the adjudicatory process," 404 U.S. at 513, and *Allied Tube*'s statement that "the applicability of *Noerr* immunity" depends on the "context and nature of the activity" undertaken, 486 U.S. at 499-500. *See, e.g.*, Pet. 29, 32. And they point to *Walker Process*'s holding that antitrust liability can flow from "enforcement of a patent procured by fraud on the Patent Office." Pet. 32 (quoting 382 U.S. at 174); *see also* Amicus Br. of Open Markets Inst. 6-7 (discussing these cases).

These statements "are necessarily limited by their respective contexts." U.S. *Armstrong* Br., 2000 WL 34005427, at *12. *Omni* "limited" *California Motor* to "th[e] situation" in which "participation in the government process [is] itself claimed to be a 'sham,' employed as a means of imposing cost and delay." 499 U.S. at 381-382. In so doing, the Court cautioned that to extend the sham exception "to a context in which the regulatory process is being invoked genuinely, and not in a 'sham' fashion, would produce precisely that conversion of antitrust law into regulation of the political process that [this Court] ha[s] sought to avoid." *Id*. at 382.

Allied Tube was similarly careful to point out that damages had been awarded only for the effect that the private electrical safety standard wrongfully procured by the defendant "had of its own force in the marketplace," not for "injuries stemming from the adoption of

the 1981 Code by governmental entities." 486 U.S. 498. And *Walker Process* turned on "the antitrust defendant's attempt to *enforce* a fraudulently procured patent directly against a would-be competitor." U.S. *Armstrong* Br., 2000 WL 34005427, at *13.

Omni, *Allied Tube*, and *Walker Process* are thus examples where the antitrust defendant "merely sought to *use process* to injure [a] competitor." *Id*. (emphasis added). Petitioners conceded "that they 'do not allege injury from the process.'" Pet. App. 15a. Even under Petitioners' preferred cases, then, their concession would be fatal.

CONCLUSION

The petition for a writ of certiorari should be denied.

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